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Office Of Public Health & Science & FDA, HHS  
Dockets Management Branch (HFA-305)  
Docket Number 02N-0466  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061, Rockville, MD 20852

RE: Solicitation Of Public Review and Comment of Research Protocol: A Multicenter,  
Randomized Dose Response Study of the Safety, Clinical and Immune Response of  
Dryvox Administered to Children 2 to 5 years of Age  
Docket No. 02N-0466

To Whom It May Concern:

I am writing to you to express my feelings and opinions about the potential experimentation of the smallpox immunization on children 2 to 5 years of age. I believe the risks of this experiment outweigh the benefits.

There are many risks that should be taken into consideration when immunizing these children. Small children are very apt to touch the infected area where the vaccine is given. The disease could then be very easily spread to others. In addition the child could cause infection by touching his own mouth or eyes. An article entitled "Feds Seek Public Input on Vaccine" states, "If the virus spread to the eye, for instance, it could cause blindness."

There is also a very strong ethical position to consider. That is, should healthy children be put at risk of a potentially life-threatening disease? These children do not even have a voice in what is being done to them. There is also the possibility that the government might be offering a payment for children to participate. This might attract parents in need of money. If this is so, the government is more likely to get underprivileged, lower class children, who are more likely to have other health issues that could complicate the immunization process.

Furthermore, the children's social interactions will be brought to a halt because they will be isolated from friends and family for the necessary period of time. Even a period of a few weeks at that young age can effect the child's social development. It is also a burden on the family to maintain this kind of isolation on such a young, active child.

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Also, this study is designed to include only a few dozen children. In order to get a valid result there needs to be a greater number in the sample population. Since there is not going to be a greater sample population what is the point of putting a few innocent children at risk when there are limited benefits.

Finally, there is no benefit of this vaccine for children because there is no smallpox threat. In comparison, when the polio vaccine was being experimented with there was a significant threat of polio to children. There were hundreds of children affected by that disease. It was necessary at the time to give the polio vaccine because there was a great threat. However, there is no threat of smallpox at this time.

It is my firm belief that the smallpox trials on children are not necessary at this time. They are potentially harmful and dangerous. The risks outweigh the benefits. I would strongly encourage the FDA not to proceed with these experimentations. Thank you for your time and consideration.

Sincerely,  
Dena Farber

*Dena Farber*